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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., SANDOZ INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action Nos. 3:11-cv-03962-MLC-DEA and 3:11-cv-5579-MLC-DEA (consolidated)

SANDOZ INC.'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT
OF NON-INFRINGEMENT OF U.S. PATENT NO. 8,598,219

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Defendant Sandoz Inc. ("Sandoz") moves for partial summary judgment of non-infringement under Federal Rule of Civil Procedure 56 and Rule 56.1 of the Local Rules of the United States District Court for the District of New Jersey with respect to the 0.075 mg/1.5 mL palonosetron intravenous product in Sandoz's ANDA No. 202521 (the "0.075 mg/1.5 mL product"). For the reasons set forth below, Sandoz is entitled to summary judgment that this product does not infringe claims 1, 2, 6, and 7 of U.S. Patent No. 8,598,219 ("the '219 patent").

I. INTRODUCTION

Sandoz's 0.075 mg/1.5 mL product contains 0.075 mg of palonosetron in a volume of 1.5 mL. This product simply cannot infringe the claims of the '219 patent that expressly call for a "single-use, unit-dose formulation" with ***0.25 mg*** palonosetron in a volume of ***5 mL*** -- and all of them do**.** In other words, each of the asserted claims requires ***three times*** the dose, and ***three times*** the volume, of Sandoz's 0.075 mg/1.5 mL product. Plaintiffs have no legitimate claim that this product could infringe the '219 patent.

The undisputed material facts in this case establish the following:

1. each of the asserted claims requires, among other things, a 5 mL solution containing 0.25 mg palonosetron hydrochloride (as the active pharmaceutical ingredient ("API"));
2. Sandoz's 0.075 mg/1.5 mL product is a 1.5 mL solution;
3. Sandoz's 0.075 mg/1.5 mL product contains 0.075 mg palonosetron hydrochloride.

Given these undisputed material facts, the issue presented in this motion is a narrow one: does a 1.5 mL solution with 0.075 mg API meet the limitations of a claim that requires a solution with three times as much as both the volume and the amount of the API? The answer is an inescapable no.

To date, Helsinn has not made, or even attempted to make, any showing to suggest that the answer to the above question is otherwise. Nevertheless, Helsinn has refused to concede non-infringement with respect to Sandoz's 0.075 mg/1.5 mL product, forcing Sandoz to bring this motion to the Court.

Moreover, if Helsinn is correct that the '219 patent is limited to use for chemotherapy-induced nausea and vomiting ("CINV"), Sandoz's 0.075 mg/1.5mL product does not infringe for yet another reason – this product is specifically indicated for post-operative nausea and vomiting ("PONV"), not CINV.

For the reasons discussed herein, Helsinn's infringement claims against Sandoz's 0.075 mg/1.5 mL product with respect to the '219 patent are baseless and must be dismissed.

II. STATEMENT OF FACTS

A. THE ASSERTED CLAIMS OF THE '219 PATENT

The '219 patent claims pharmaceutical single-use, unit-dose formulations of palonosetron. (SOF ¶ 2.)[1] Claim 1 is the only independent claim among the asserted claims:

> 1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human ***to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting***, comprising ***a 5 mL sterile aqueous isotonic solution***, said solution comprising:
>
> ***palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base***;
>
> from 0.005 mg/mL to 1.0 mg/mL EDTA;
>
> and from 10 mg/mL to 80 mg/mL mannitol,
>
> wherein said formulation is stable at 24 months when stored at room temperature.

(Ex. A at 10:2-12 (emphasis added).) Claims 2, 6 and 7 each depends on claim 1 with additional limitations. (SOF ¶¶ 3-5.)

The parties do not dispute that all of the asserted claims should be given their plain and ordinary meaning. (*See* Dkt. No. 175, at 2.) As highlighted in

[1] A Rule 56.1 Statement of Undisputed Material Facts ("Rule 56.1 Statement") is submitted herewith, and citations thereto take the form "SOF ¶ __." Reference herein to "Ex. __" refers to an exhibit to the Declaration of Matthew M. D'Amore, submitted in support of this memorandum and the Rule 56.1 Statement.

claim 1, the plain and ordinary meaning of the asserted claims requires a 5 mL solution containing 0.25 mg palonosetron hydrochloride.

B. SANDOZ'S ANDA NO. 202521 AND 0.075 MG/1.5 ML PRODUCT

Sandoz's ANDA No. 202521 seeks approval for two palonosetron injection products for two distinct indications: a 0.25 mg/5 mL product for controlling CINV and a 0.075 mg/1.5 mL product for controlling PONV. (SOF ¶¶ 6-11.)

This motion is focused exclusively on the 0.075 mg/1.5 mL product, which does not infringe any of the asserted claims.[2] ANDA No. 202521 describes this product: it has a total content of palonosetron hydrochloride of 0.075 mg and a solution fill volume of 1.5 mL. (SOF ¶¶ 8-9.) In addition, the proposed drug label of ANDA No. 202521 states that this product is indicated for treating PONV in adults. (SOF ¶ 10.)

[2]Based on discussions prior to the filing of this motion, Helsinn is expected to contend that Sandoz is not entitled to judgment because Sandoz's ANDA includes the 0.25 mg/5mL dosage form, which Helsinn does affirmatively discuss in its contentions. Helsinn appears to contend that this would lead to a judgment of infringement as to the 0.075 mg/1.5 mL product as well. Helsinn is wrong – an ANDA cannot infringe a patent. *Ferring B.V. v. Watson Labs., Inc.-Florida*, Civ No. 2014-1416, --- F.3d ---, 2014 WL 4116461, at *7 (Fed. Cir. Aug. 22, 2014). Instead, "[t]he filing [of an ANDA] only constituted a technical act of infringement for jurisdictional purposes." *Id.* The ultimate infringement determination, on the other hand, must be based on "a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles." *Id.*

[redacted]

C. HELSINN'S ALLEGATIONS OF INFRINGEMENT.

On December 27, 2013, Helsinn filed an Amended Complaint in this litigation alleging, *inter alia*, that both of Sandoz's proposed ANDA products infringe the '219 patent. (SOF ¶¶ 12-13.) On March 17, 2014, Sandoz served its Non-Infringement Contentions. (Ex. E.) Sandoz's contentions included a written explanation and a claim chart that specifically explained why the 0.075 mg/1.5 mL product does not meet all the limitations of, and thus cannot infringe, the asserted claims of the '219 patent. (SOF ¶¶ 14-16.)

In response, Helsinn served its Infringement Contentions on May 2, 2014. (Ex. F.) In its contentions, however, Helsinn fails to distinguish between the 0.25 mg/5 mL product and the 0.075 mg/1.5 mL product. (SOF ¶¶ 17-20.) Helsinn's claim chart that allegedly "identif[ies] where each limitation of each asserted claim is found within Sandoz's proposed ANDA ***products***" also completely ignores the 0.075 mg/1.5 mL product. (Ex. F at 4, 7-10 (emphasis added); SOF ¶¶ 17-20.) Helsinn also makes no infringement claim against the 0.075 mg/1.5 mL product under the doctrine of equivalents. (SOF ¶ 20.)

On August 15, 2014, Helsinn served the Expert Report of Gordon L. Amidon Regarding Infringement of U.S. Patent No. 8,598,219 to purportedly support Helsinn's infringement claims against Sandoz's ANDA. (Ex. G; SOF ¶ 21.) Notably, however, Dr. Amidon's infringement analysis is again based on

the 0.25 mg/5 mL product. (SOF ¶¶ 22-24.) Dr. Amidon's report contains no analysis as to how the 0.075 mg/1.5 mL product would meet the limitations of a 5 mL solution containing 0.25 mg palonosetron hydrochloride. (*Id.*) Neither has he performed any doctrine of equivalent analysis. (SOF ¶ 24.)

III. ARGUMENT

Based on the undisputed facts, Sandoz's 0.075 mg/1.5mL product does not meet the dosage limitations of the asserted claims of the '219 patent. In addition, if Helsinn is correct that the use for CINV is a limitation of the '219 patent, Sandoz's 0.075 mg/1.5mL product does not meet that limitation and therefore does not infringe for that reason as well.

A. LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact" and "the movant is entitled to judgment as a matter of law." Fed. R. CIV. P. 56(a). The moving party bears the initial burden of proving the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to "designate 'specific facts showing that there is a genuine issue for trial.'" *Id*. at 324.

The framework for an infringement analysis is a two-step process: (1) determination of the correct claim scope; and (2) comparison of the properly construed claim to the accused device to determine whether all of the claim

limitations are present either literally or by a substantial equivalent. *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1247–48 (Fed. Cir. 1998). "[A]n accused infringer seeking summary judgment of noninfringement may meet its initial responsibility . . . by providing evidence that would preclude a finding of infringement." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001).

For literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Any deviation from the literal claim language precludes a literal infringement finding. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001). Infringement under the doctrine of equivalents requires "equivalence between those elements of the accused product and the claimed limitations of the patented invention that are not literally infringed." *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316 (Fed. Cir. 1999). "Equivalence" means that the elements of the accused product are insubstantially different from the claimed limitation or that they perform substantially the same function as the claimed structure, in substantially the same way, to achieve the same result. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 (1997).

In a Hatch-Waxman case, the infringement determination is based on "a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles." *Ferring B.V.*, 2014 WL 4116461, at *7. Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, the ANDA specification may often be able to directly resolve the question as to whether the proposed product infringes the asserted patent claims. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-50 (Fed. Cir. 2000) (finding that proposed generic product did not infringe based on the ANDA specification of the product); *see also In re Brimonidine Patent Litig.*, 643 F.3d 1366, 1377 (Fed. Cir. 2011) (finding that the content of the ANDA control[s] the infringement inquiry as to the proposed product).

B. SANDOZ'S 0.075 MG/1.5 ML PRODUCT DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '219 PATENT BECAUSE IT DOES NOT PROVIDE THE REQUIRED DOSAGE OR VOLUME.

As shown above, Sandoz's 0.075 mg/1.5 mL product does not literally infringe any of the asserted claims for at least the following two reasons. *First*, the asserted claims require a formulation containing "palonosetron hydrochloride in an amount of 0.25 mg," while Sandoz's 0.075 mg/1.5 mL product includes only 0.075 mg palonosetron hydrochloride. (SOF ¶¶ 2-9.) *Second*, the asserted claims

require a formulation that has "a 5 mL sterile aqueous isotonic solution," while Sandoz's 0.075 mg/1.5 mL product has a volume of only 1.5 mL. (SOF ¶¶ 2-9.)

Sandoz's 0.075 mg/1.5 mL product also does not infringe any of the asserted claims under the doctrine of equivalents ("DOE"). As an initial matter, Helsinn has not made any infringement contention under the DOE against this product. (SOF ¶¶ 20, 24.) It has accordingly waived any such claim. In any event, Helsinn cannot demonstrate "equivalence between those elements of the accused product and the [missing] claimed limitations." *Zelinski*, 185 F.3d at 1316.

First, the 0.075 mg amount of API in the proposed product is more than three times less than the API amount (i.e., 0.25 mg) required by the asserted claims. 0.075 mg cannot be equivalent to 0.25 mg. *See Tegal Corp. v. Tokyo Electron Co.*, Civ. Nos. 01-1019, 01-1020, 2002 U.S. App. Lexis 1992, at *13-14 (Fed. Cir. Feb. 1, 2002) (finding that because 2 MHz is twice 1 MHz, a finding of equivalence between the two would vitiate a claim limitation that requires less than about 1 MHz). *Second*, the 1.5 mL volume of the proposed product is also more than three times lower than the solution volume (i.e., 5 mL) required by the asserted claims. Again, 1.5 mL cannot be equivalent to 5 mL. *Id*.

[redacted]

C. SANDOZ'S 0.075 MG/1.5 ML PRODUCT DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '219 PATENT BECAUSE IT IS NOT INDICATED FOR CINV

As set forth in their Markman briefing, Helsinn asserts that the intended use of the formulation claimed by the asserted claims, "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting," is a limitation of those claims. *See* Dkt. No. 177. Sandoz does not agree with Plaintiffs' position. But if Plaintiffs are correct, the 0.075 mg/1.5 mL product does not infringe the '219 patent for an additional reason – it is not indicated for CINV, but rather PONV. (SOF ¶¶ 10-11.) Plaintiffs have pointed to no evidence from Sandoz's ANDA that the 0.075 mg/1.5 mL product is addressed to CINV. There is none.

IV. CONCLUSION

For the reasons set forth above, Sandoz respectfully requests that the Court grant its motion for partial summary judgment of non-infringement of the '219 patent with respect to its 0.075 mg/1.5 mL product.

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